



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

MAR 20 2001

TECH CENTER 1600/2900

In re application of: HU et al.

Application Serial No.: 09/219,442

Art Unit: 1647

Filed: December 23, 1998

Examiner: Saoud, C.

For: Vascular Endothelial Growth Factor 2

Attorney Docket No.: PF112P2D1

#17
P. 8
3/27/01

RESPONSE UNDER 37 C.F.R. § 1.111 TO PAPER NO. 14

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action mailed September 19, 2000 (Paper No. 14), Applicants hereby request that the Examiner's rejections be removed in light of the remarks enclosed herein. Applicants submit concurrently herewith: (a) a Petition for Extension of Time for three (3) months up to and including March 19, 2001; (b) a Fee Transmittal, with appropriate fee(s); (c) Supplemental Information Disclosure Statement with Form PTO/SB/08A, references EA-EW, and Seven (7) Statutory Declarations and accompanying exhibits/documents; (d) Power of Attorney By Assignee of Entire Interest/Revocation of Prior Power of Attorney and Exhibit 1; and (e) Request for Correction of Filing Receipt and copy of Filing Receipt with corrections marked in red ink.

Remarks

Claims 33-446 are pending in this application. Applicants respectfully request reconsideration of the rejections in view of the following remarks.

Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 33-446 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter

which applicants regard as the invention, on the grounds of multiplicity. In support of this contention, the Examiner cited M.P.E.P. § 2173.05(n), stating that:

[a]n unreasonable number of claims, that is, unreasonable in view of the nature and scope of applicant's invention and the state of the art, may afford a basis for a rejection on the ground of multiplicity. A rejection on this ground should include all the claims in the case inasmuch as it related to confusion of the issue.

M.P.E.P. § 2173.05(n). Relying on this, the Examiner stated that Applicants should elect 50 claims for the purposes of examination. Applicants respectfully disagree with the Examiner's reasoning and traverse this rejection.

The United States Court of Customs and Patent Appeals (CCPA) has held that the applicant is allowed to determine the number and scope of the claims, provided that the applicant pays the required fees and otherwise operates within the statutory requirements. *In re Wakefield*, 422 F.2d 897, 901. Applicants are aware of no statutory requirements that require Applicants to limit the number of claims to 50. Applicants have also paid the required fees for prosecuting the pending claims. Thus, Applicants have followed permissible caselaw and statutory requirements and merely added a prudent set of claims of a different scope by which to protect their invention. Applicants respectfully request that the Examiner withdraw the rejection of claims 33-446.

The Examiner further rejects claims 33-446 as subject matter which repeats "what is already claimed and patented." Applicants respectfully disagree. Claims 33-446 contain independent product by process claims, with corresponding dependent claims of a different scope. The M.P.E.P. states in pertinent part that "A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." M.P.E.P. § 2173.05(p)

By contrast, the subject matter claimed and patented in U.S. Patent 5,932,540, is directed to VEGF-2 compositions made by any process (e.g., chemical synthesis, see, for example, page 27, line 6). As Table 1 demonstrates, pending claims 33-446 of the instant application do not claim subject matter already claimed and patented. For example, independent claim 33 of the pending application claims a purified mature protein of a polypeptide comprising the amino acid sequence of SEQ ID NO:4, produced by the method comprising:

- (a) expressing a mature protein of a polypeptide comprising the amino acid sequence of SEQ ID NO:4 from a host cell; and

(b) recovering said mature protein.

By contrast, claim 1 of U.S. Patent 5,932,540 claims an isolated polypeptide comprising a mature portion of a protein consisting of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4.

As is clear, independent claim 33 of the instant application is a claimed product, defined in terms of the process used to produce it. Claim 1 of U.S. Patent 5,932,540 however is a composition claim. These independent claims have different scopes, and do not claim the same subject matter. This relationship carries for the remaining claims referenced in Table 1.

TABLE 1¹

Independent claim: A purified ____ produced by the method comprising: (a) expressing the X from a host cell; and (b) recovering said ____.	Claim Number in Pending Claim Set	Related Claim in U.S. Patent 5,932,540
X represents "a mature protein of a polypeptide comprising the amino acid sequence of SEQ ID NO:4"	33	1
X represents "a proprotein of the purified proprotein comprising the amino acid sequence of SEQ ID NO:4"	53	2
X represents "a mature protein encoded by the cDNA contained in ATCC Deposit Nos. 97149"	73	3
X represents "a proprotein encoded by the cDNA contained in ATCC Deposit Nos. 97149"	93	4
X represents "a protein encoded by the cDNA contained in ATCC Deposit Nos. 97149"	113	5
X represents "a protein comprising amino acids 131 to 144 of SEQ ID NO:2"	133	6
X represents "a protein comprising amino acids 71 to 396 of SEQ ID NO:2"	145	7
X represents "a protein comprising amino acids 24 to 396 of SEQ ID NO:2"	165	9
X represents "a protein comprising amino acids 1 to 396 of SEQ ID NO:2"	185	10
X represents "a protein comprising amino acids -23 to 396 of SEQ ID NO:2"	205	11
X represents "a protein fragment of SEQ ID NO:2...wherein said protein fragment has angiogenic activity"	225	12

¹ Table 1, column 1 identifies the product produced by the process. Table 1, column 2 identifies the independent claim setting forth the product produced by the process. Table 1, column 3 references the related claim of U.S. Patent 5,932,540.

X represents "a protein fragment encoded by the cDNA contained in ATCC Deposit No. 97149...wherein said protein fragment has angiogenic activity"	245	12
X represents "a protein fragment of SEQ ID NO:2...wherein said protein fragment has endothelial cell proliferative activity"	265	13
X represents "a protein fragment encoded by the cDNA contained in ATCC Deposit No. 97149...wherein said protein fragment has endothelial cell proliferative activity"	285	13
X represents "a protein fragment of at least 30 contiguous amino acids of SEQ ID NO:2"	305	14
X represents "a protein fragment of at least 30 contiguous amino acids of the cDNA contained in ATCC Deposit No. 97149"	326	14
X represents "a mature protein encoded by the cDNA contained in ATCC Deposit Nos. 75698"	347	3
X represents "a proprotein encoded by the cDNA contained in ATCC Deposit Nos. 75698"	367	4
X represents "a protein encoded by the cDNA contained in ATCC Deposit Nos. 75698"	387	5
X represents "a protein fragment encoded by the cDNA contained in ATCC Deposit No. 75698...wherein said protein fragment has angiogenic activity"	407	12
X represents "a protein fragment encoded by the cDNA contained in ATCC Deposit No. 75698...wherein said protein fragment has endothelial cell proliferative activity"	427	13

Each independent claim referenced in column 2 of Table 1 has a corresponding set of dependent claims that are different in scope. For example, claims 34 and 35 of the instant application depend from independent claim 33. Dependent claim 34 is directed to the product made by the process of claim 33, wherein the product is recovered from a *natural* source. Dependent claim 35 is also directed to the product made by the process of claim 33, however dependent claim 35 is directed to the product recovered from a *recombinant host cell* engineered to express the product. Clearly, claims 34 and 35 further limit the scope of claim 33.

Similarly, claims 40 and 41 of the instant application depend from independent claim 33. Dependent claim 40 is directed to the product made by the process of claim 33, wherein the product is recovered by *chromatography*. Dependent claim 41 is also directed to the product made by the process of claim 33, however dependent claim 41 is directed to the product recovered by an *antibody*. Again, claims 40 and 41 further limit claim 33.

Each of the dependent claim sets claim subject matter different from that of U.S. Patent 5,932,540. Furthermore, each dependent claim contained within the instant application claims subject matter different in scope than the remaining dependent claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 33-446 under 35 U.S.C. § 112, second paragraph. Applicants have demonstrated that the pending claims do not cloud the issue to the extent that would warrant a continuation of the multiplicity rejection. Applicants may submit as many claims as may be deemed necessary, provided that Applicants pay the necessary fees and otherwise operate within the statutory requirements. Furthermore, Applicants have shown that the pending claims are directed to products made by a process, in contrast to the claims of Issued Patent 5,932,540. Thus, the pending claims are not directed to subject matter that is already claimed and patented.

Conflicting Claims:

The Examiner rejected the method claims of the present application as conflicting with claims 22-110 of Application No. 09/107,997, according to 37 CFR 1.78 (b). See Paper No. 14, Page 4, paragraph 1. Applicants respectfully disagree. The pending method claims of the instant application do not conflict with claims 22-110 of Application No. 09/107,997 because the method claims depend from products made by a particular process, whereas pending claims 22-110 of Application No. 09/107,997 are directed to a method of stimulating angiogenesis using VEGF-2 polypeptides (wherein the VEGF-2 polypeptides can be made by any process).

For the same reasons stated above, the claims of the instant application are different in both subject matter and scope from the claims of pending application 09/107,997. Claims 33-446 contain independent product by process claims, with corresponding dependent claims of a different scope. By contrast, the subject matter claimed in pending application 09/107,997 is directed to a method of stimulating angiogenesis using VEGF-2 polypeptides, and not limited to a particular process.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to pending claims 33-446 as conflicting with pending claims 22-110 of Application No. 09/107,997, according to 37 CRF 1.78 (b).

Associate Power

Applicants enclose herewith an executed Power of Attorney By Assignee of Entire Interest/Revocation of Prior Power of Attorney ("Power of Attorney"). This Power of Attorney appoints Michele M. Wales as an attorney of record for the instant application.

Conclusion

In view of the foregoing remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. A request is made to the Examiner to call the undersigned at the phone number provided below if any further action by Applicants would expedite allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: March 16, 2001 
Michele M. Wales (Reg. No. 43,975)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (301) 610-5772

Enclosures
MMW/RL/lcc